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Senju Pharmaceutical Co., Ltd.,  
Bausch & Lomb Incorporated, and  
Bausch & Lomb Pharma Holdings Corp.*

**UNITED STATES DISTRICT COURT  
DISTRICT OF NEW JERSEY**

SENJU PHARMACEUTICAL CO., LTD.;  
BAUSCH & LOMB INCORPORATED; and  
BAUSCH & LOMB PHARMA HOLDINGS  
CORP.,

Plaintiffs,

AUROBINDO PHARMA USA INC. and  
AUROBINDO PHARMA LIMITED,

Defendants.

Civil Action No. \_19-13348\_\_\_\_\_

*Document Electronically Filed*

**COMPLAINT FOR PATENT INFRINGEMENT**

Plaintiffs Senju Pharmaceutical Co., Ltd. (“Senju”), Bausch & Lomb Incorporated (“B+L”) and Bausch & Lomb Pharma Holdings Corp. (“B+L Pharma Holdings”) (collectively, “Plaintiffs”), by way of Complaint against Defendants Aurobindo Pharma USA Inc. (“Aurobindo USA”) and Aurobindo Pharma Limited (“Aurobindo India”) (collectively, “Aurobindo” or “Defendants”), allege as follows:

### **THE PARTIES**

1. Plaintiff Senju is a corporation organized and existing under the laws of Japan, with a principal place of business at 3-1-9, Kawaramachi, Chuo-ku, Osaka 541-0048, Japan.

2. Plaintiff B+L is a corporation organized and existing under the laws of New York, with a place of business at 1400 North Goodman St., Rochester, New York 14609. B+L is the registered holder of approved New Drug Application (“NDA”) No. 203168, which covers Prolensa®.

3. Plaintiff B+L Pharma Holdings is a corporation organized and existing under the laws of Delaware, with a place of business at 700 Route 202/206, Bridgewater, New Jersey 08807. B+L Pharma Holdings is a wholly-owned subsidiary of B+L.

4. Upon information and belief, Defendant Aurobindo USA is a corporation organized and existing under the laws of Delaware, having its principal place of business at 279 Princeton-Hightstown Road, East Windsor, New Jersey 08520. Upon information and belief, Aurobindo USA is a wholly-owned subsidiary of Aurobindo India.

5. Upon information and belief, Defendant Aurobindo India is a corporation organized and existing under the laws of India, having its principal place of business at Plot #2, Maitrivihar, Ameerpat, Hyderabad - 5000038, Telangana, India.

### **NATURE OF THE ACTION**

6. This is an action for infringement of United States Patent Nos. 8,129,431 (“the ’431 patent”), 8,669,290 (“the ’290 patent”), 8,754,131 (“the ’131 patent”), 8,871,813 (“the ’813 patent”), 8,927,606 (“the ’606 patent”), 9,144,609 (“the ’609 patent”), 9,517,220 (“the ’220 patent”), 9,561,277 (“the ’277 patent”), and 10,085,958 (“the ’958 patent”), arising under the United States patent laws, Title 35, United States Code, § 100 et seq., including 35 U.S.C. §§ 271

and 281. This action relates to Aurobindo's filing of an Abbreviated New Drug Application ("ANDA") under Section 505(j) of the Federal Food, Drug, and Cosmetic Act ("the Act"), 21 U.S.C. § 355(j), seeking U.S. Food and Drug Administration ("FDA") approval to market its generic bromfenac ophthalmic solution (0.07%) ("Aurobindo's generic bromfenac ophthalmic solution") before the expiration of the asserted patents.

### **JURISDICTION AND VENUE**

7. This Court has subject matter jurisdiction under 28 U.S.C. §§ 1331, 1338(a), and 2201-02.

8. Upon information and belief, this Court has jurisdiction over Aurobindo USA. Upon information and belief, Aurobindo USA is in the business of, *inter alia*, developing, manufacturing, marketing, importing, distributing, and selling pharmaceutical drug products, including generic drug products. Upon information and belief, Aurobindo USA directly, or indirectly, develops, manufactures, markets, imports, distributes, and sells generic drug products throughout the United States and in this judicial district, and this judicial district is a likely destination for Aurobindo's generic bromfenac ophthalmic solution. Upon information and belief, Aurobindo USA purposefully has conducted and continues to conduct business in this judicial district.

9. Upon information and belief, Aurobindo USA has its principal place of business at 279 Princeton-Hightstown Road, East Windsor, New Jersey 08520. Upon information and belief, Aurobindo USA also operates a "Distribution Center" located at 6 Wheeling Road, Dayton, New Jersey, 08810.

10. Upon information and belief, Aurobindo USA has previously admitted to, consented to, or has not contested the jurisdiction of this Court in prior District of New Jersey

actions, including, for example: *Valeant Pharms. North America LLC et al. v. Aurobindo Pharma USA, Inc. et al.*, Civil Action No. 3:18-13693; *Celgene Corp. v. Aurobindo Pharma Ltd. et al.*, Civil Action No. 2:19-00143; *Forest Labs, LLC et al. v. Aurobindo Pharma USA, Inc. et al.*, Civil Action No. 2:17-11679; and *Otsuka Pharma Co. Ltd. v. Aurobindo Pharma Ltd. et al.*, Civil Action No. 1:14-03306.

11. Aurobindo USA has previously availed itself of the rights, benefits, and privileges of this Court by asserting counterclaims in prior District of New Jersey actions, including, for example: *Valeant Pharms. North America LLC et al. v. Aurobindo Pharma USA, Inc. et al.*, Civil Action No. 3:18-13693; *Celgene Corp. v. Aurobindo Pharma Ltd. et al.*, Civil Action No. 2:19-00143; *Forest Labs, LLC et al. v. Aurobindo Pharma USA, Inc. et al.*, Civil Action No. 2:17-11679; and *Otsuka Pharma Co. Ltd. v. Aurobindo Pharma Ltd. et al.*, Civil Action No. 1:14-03306.

12. Upon information and belief, this Court has jurisdiction over Aurobindo India. Upon information and belief, Aurobindo India is in the business of, *inter alia*, developing, manufacturing, marketing, importing, distributing, and selling pharmaceutical drug products, including generic drug products. Upon information and belief, Aurobindo India directly, or indirectly, manufactures, markets, distributes, and sells generic drug products throughout the United States and in this judicial district, and this judicial district is a likely destination for Aurobindo's generic bromfenac ophthalmic solution. Upon information and belief, Aurobindo India purposefully has conducted and continues to conduct business in this judicial district.

13. Upon information and belief, Aurobindo India has previously admitted to, consented to, or has not contested the jurisdiction of this Court in prior District of New Jersey actions, including, for example: *Valeant Pharms. North America LLC et al. v. Aurobindo Pharma USA, Inc. et al.*, Civil Action No. 3:18-13693; *Celgene Corp. v. Aurobindo Pharma Ltd. et al.*,

Civil Action No. 2:19-00143; *Forest Labs, LLC et al. v. Aurobindo Pharma USA, Inc. et al.*, Civil Action No. 2:17-11679; and *Otsuka Pharma Co. Ltd. v. Aurobindo Pharma Ltd. et al.*, Civil Action No. 1:14-03306.

14. Aurobindo India has previously availed itself of the rights, benefits, and privileges of this Court by asserting counterclaims in prior District of New Jersey actions, including, for example: *Valeant Pharms. North America LLC et al. v. Aurobindo Pharma USA, Inc. et al.*, Civil Action No. 3:18-13693; *Celgene Corp. v. Aurobindo Pharma Ltd. et al.*, Civil Action No. 2:19-00143; *Forest Labs, LLC et al. v. Aurobindo Pharma USA, Inc. et al.*, Civil Action No. 2:17-11679; and *Otsuka Pharma Co. Ltd. v. Aurobindo Pharma Ltd. et al.*, Civil Action No. 1:14-03306.

15. Aurobindo India has taken the costly, significant step of applying to the FDA for approval to engage in future activities—including the marketing of Aurobindo’s generic bromfenac ophthalmic solution—that will be purposefully directed at, upon information and belief, the State of New Jersey and elsewhere. Aurobindo India’s ANDA filing constitutes a formal act that reliably indicates plans to engage in the marketing of Aurobindo’s generic bromfenac ophthalmic solution. Upon information and belief, Aurobindo India intends to direct sales of Aurobindo’s generic bromfenac ophthalmic solution into New Jersey, among other places, once it has the requested FDA approval to market it. Upon information and belief, Aurobindo India will engage in the marketing of Aurobindo’s generic bromfenac ophthalmic solution in New Jersey upon approval of its ANDA.

16. Upon information and belief, Aurobindo USA and Aurobindo India work in concert with each other with respect to the regulatory approval, manufacturing, marketing, distribution, and sale of generic pharmaceutical products throughout the United States, including in this judicial district.

17. Upon information and belief, venue is proper in this judicial district under 28 U.S.C. §§ 1391(b), 1391(c), and 1400(b).

18. Venue is proper against Aurobindo USA because it operates a principal place of business in this judicial district.

19. Venue is proper against Aurobindo India, a foreign corporation, in any judicial district that has personal jurisdiction, including this judicial district.

### **THE PATENTS IN SUIT**

20. The U.S. Patent and Trademark Office (“PTO”) issued the ’431 patent on March 6, 2012. The ’431 patent claims, *inter alia*, formulations of bromfenac for ophthalmic administration. Plaintiffs hold all substantial rights in the ’431 patent and have the right to sue for infringement thereof. Senju is the assignee of the ’431 patent. A copy of the ’431 patent is attached hereto as Exhibit A.

21. The PTO issued the ’290 patent on March 11, 2014. The ’290 patent claims, *inter alia*, formulations of bromfenac for ophthalmic administration. Plaintiffs hold all substantial rights in the ’290 patent and have the right to sue for infringement thereof. Senju is the assignee of the ’290 patent. A copy of the ’290 patent is attached hereto as Exhibit B.

22. The PTO issued the ’131 patent on June 17, 2014. The ’131 patent claims, *inter alia*, formulations of bromfenac for ophthalmic administration. Plaintiffs hold all substantial rights in the ’131 patent and have the right to sue for infringement thereof. Senju is the assignee of the ’131 patent. A copy of the ’131 patent is attached hereto as Exhibit C.

23. The PTO issued the ’813 patent on October 28, 2014. The ’813 patent claims, *inter alia*, formulations of bromfenac for ophthalmic administration. Plaintiffs hold all substantial rights in the ’813 patent and have the right to sue for infringement thereof. Senju is the assignee of the

'813 patent. A copy of the '813 patent is attached hereto as Exhibit D.

24. The PTO issued the '606 patent on January 6, 2015. The '606 patent claims, *inter alia*, formulations of bromfenac for ophthalmic administration. Plaintiffs hold all substantial rights in the '606 patent and have the right to sue for infringement thereof. Senju is the assignee of the '606 patent. A copy of the '606 patent is attached hereto as Exhibit E.

25. The PTO issued the '609 patent on September 29, 2015. The '609 patent claims, *inter alia*, formulations of bromfenac for ophthalmic administration. Plaintiffs hold all substantial rights in the '609 patent and have the right to sue for infringement thereof. Senju is the assignee of the '609 patent. A copy of the '609 patent is attached hereto as Exhibit F.

26. The PTO issued the '220 patent on December 13, 2016. The '220 patent claims, *inter alia*, formulations of bromfenac for ophthalmic administration. Plaintiffs hold all substantial rights in the '220 patent and have the right to sue for infringement thereof. B+L Pharma Holdings is the assignee of the '220 patent. A copy of the '220 patent is attached hereto as Exhibit G.

27. The PTO issued the '277 patent on February 7, 2017. The '277 patent claims, *inter alia*, formulations of bromfenac for ophthalmic administration. Plaintiffs hold all substantial rights in the '277 patent and have the right to sue for infringement thereof. Senju is the assignee of the '277 patent. A copy of the '277 patent is attached hereto as Exhibit H.

28. The PTO issued the '958 patent on October 2, 2018. The '958 patent claims, *inter alia*, formulations of bromfenac for ophthalmic administration. Plaintiffs hold all substantial rights in the '958 patent and have the right to sue for infringement thereof. B+L Pharma Holdings is the assignee of the '958 patent. A copy of the '958 patent is attached hereto as Exhibit I.

29. B+L is the holder of NDA No. 203168 for Prolensa®, which the FDA approved on April 5, 2013. In conjunction with NDA No. 203168, the '431 patent, the '290 patent, the '131

patent, the '813 patent, the '606 patent, the '609 patent, the '220 patent, the '277 patent, and the '958 patent are listed in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations ("the Orange Book").

30. Bromfenac ophthalmic solution 0.07% is sold in the United States under the trademark Prolensa®.

### **AUROBINDO'S INFRINGING ANDA SUBMISSION**

31. Upon information and belief, Aurobindo filed with the FDA ANDA No. 212964 under Section 505(j) of the Act and 21 U.S.C. § 355(j).

32. Upon information and belief, Aurobindo's ANDA No. 212964 seeks FDA approval to sell in the United States Aurobindo's generic bromfenac ophthalmic solution, intended to be a generic version of Prolensa®.

33. Plaintiffs received a letter from Aurobindo dated April 19, 2019, purporting to be a Notice of Certification for ANDA No. 212964 ("Aurobindo's Notice Letter") under Section 505(j)(2)(B)(ii) of the Act, 21 U.S.C. § 355(j)(2)(B)(ii), and 21 § C.F.R. 314.95.

34. Aurobindo's notice letter alleges that Aurobindo has submitted to the FDA ANDA 212964 seeking FDA approval to sell in the United States Aurobindo's generic bromfenac ophthalmic solution, intended to be a generic version of Prolensa®.

35. Aurobindo's notice letter, which is required by statute and regulation to provide a full and detailed explanation regarding any non-infringement defenses, does not allege meritorious non-infringement defenses for any of the claims of the '431 patent, the '290 patent, the '131 patent, the '813 patent, the '606 patent, the '609 patent, the '220 patent, the '277 patent, or the '958 patent.

36. Upon information and belief, ANDA No. 212964 seeks approval of Aurobindo's generic bromfenac ophthalmic solution, that is the same, or substantially the same, as Prolensa®.



## **COUNT I AGAINST AUROBINDO**

### **Infringement of the '431 Patent under § 271(e)(2)**

37. Paragraphs 1-36 are incorporated herein as set forth above.

38. Under 35 U.S.C. § 271(e)(2), Aurobindo has infringed at least one claim of the '431 patent by submitting, or causing to be submitted, to the FDA ANDA No. 212964 seeking approval for the commercial marketing of Aurobindo's generic bromfenac ophthalmic solution before the expiration of the '431 patent.

39. Upon information and belief, Aurobindo's generic bromfenac ophthalmic solution will, if approved and marketed, infringe at least one claim of the '431 patent.

40. Upon information and belief, Aurobindo will, through the manufacture, use, import, offer for sale, and/or sale of Aurobindo's generic bromfenac ophthalmic solution, directly infringe, contributorily infringe, and/or induce infringement of at least one claim of the '431 patent.

41. If Aurobindo's marketing and sale of its generic bromfenac ophthalmic solution prior to the expiration of the '431 patent is not enjoined, Plaintiffs will suffer substantial and irreparable harm for which there is no adequate remedy at law.

## **COUNT II AGAINST AUROBINDO**

### **Declaratory Judgment of Infringement of the '431 Patent**

42. Paragraphs 1-41 are incorporated herein as set forth above.

43. These claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

44. There is an actual case or controversy such that the Court may entertain Plaintiffs' request for declaratory relief consistent with Article III of the United States Constitution, and this actual case or controversy requires a declaration of rights by this Court.

45. Aurobindo has made, and will continue to make, substantial preparations in the United States to manufacture, use, offer to sell, sell, and/or import Aurobindo's generic bromfenac ophthalmic solution before the expiration of the '431 patent, including Aurobindo's filing of ANDA No. 212964.

46. Upon information and belief, any commercial manufacture, use, offer for sale, sale, and/or importation of Aurobindo's generic bromfenac ophthalmic solution will directly infringe, contributorily infringe, and/or induce infringement of at least one claim of the '431 patent.

47. Plaintiffs are entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, sale, and/or importation of Aurobindo's generic bromfenac ophthalmic solution will constitute infringement of at least one claim of the '431 patent.

### **COUNT III AGAINST AUROBINDO**

#### **Infringement of the '290 Patent under § 271(e)(2)**

48. Paragraphs 1-47 are incorporated herein as set forth above.

49. Under 35 U.S.C. § 271(e)(2), Aurobindo has infringed at least one claim of the '290 patent by submitting, or causing to be submitted, to the FDA ANDA No. 212964 seeking approval for the commercial marketing of Aurobindo's generic bromfenac ophthalmic solution before the expiration of the '290 patent.

50. Upon information and belief, Aurobindo's generic bromfenac ophthalmic solution will, if approved and marketed, infringe at least one claim of the '290 patent.

51. Upon information and belief, Aurobindo will, through the manufacture, use, import, offer for sale, and/or sale of Aurobindo's generic bromfenac ophthalmic solution, directly infringe, contributorily infringe, and/or induce infringement of at least one claim of the '290 patent.

52. If Aurobindo's marketing and sale of its generic bromfenac ophthalmic solution

prior to the expiration of the '290 patent is not enjoined, Plaintiffs will suffer substantial and irreparable harm for which there is no adequate remedy at law.

#### **COUNT IV AGAINST AUROBINDO**

##### **Declaratory Judgment of Infringement of the '290 Patent**

53. Paragraphs 1-52 are incorporated herein as set forth above.

54. These claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

55. There is an actual case or controversy such that the Court may entertain Plaintiffs' request for declaratory relief consistent with Article III of the United States Constitution, and this actual case or controversy requires a declaration of rights by this Court.

56. Aurobindo has made, and will continue to make, substantial preparations in the United States to manufacture, use, offer to sell, sell, and/or import Aurobindo's generic bromfenac ophthalmic solution before the expiration of the '290 patent, including Aurobindo's filing of ANDA No. 212964.

57. Upon information and belief, any commercial manufacture, use, offer for sale, sale, and/or importation of Aurobindo's generic bromfenac ophthalmic solution will directly infringe, contributorily infringe, and/or induce infringement of at least one claim of the '290 patent.

58. Plaintiffs are entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, sale, and/or importation of Aurobindo's generic bromfenac ophthalmic solution will constitute infringement of at least one claim of the '290 patent.

#### **COUNT V AGAINST AUROBINDO**

##### **Infringement of the '131 Patent under § 271(e)(2)**

59. Paragraphs 1-58 are incorporated herein as set forth above.

60. Under 35 U.S.C. § 271(e)(2), Aurobindo has infringed at least one claim of the '131 patent by submitting, or causing to be submitted, to the FDA ANDA No. 212964 seeking approval for the commercial marketing of Aurobindo's generic bromfenac ophthalmic solution before the expiration of the '131 patent.

61. Upon information and belief, Aurobindo's generic bromfenac ophthalmic solution will, if approved and marketed, infringe at least one claim of the '131 patent.

62. Upon information and belief, Aurobindo will, through the manufacture, use, import, offer for sale, and/or sale of Aurobindo's generic bromfenac ophthalmic solution, directly infringe, contributorily infringe, and/or induce infringement of at least one claim of the '131 patent.

63. If Aurobindo's marketing and sale of its generic bromfenac ophthalmic solution prior to the expiration of the '131 patent is not enjoined, Plaintiffs will suffer substantial and irreparable harm for which there is no adequate remedy at law.

## **COUNT VI AGAINST AUROBINDO**

### **Declaratory Judgment of Infringement of the '131 Patent**

64. Paragraphs 1-63 are incorporated herein as set forth above.

65. These claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

66. There is an actual case or controversy such that the Court may entertain Plaintiffs' request for declaratory relief consistent with Article III of the United States Constitution, and this actual case or controversy requires a declaration of rights by this Court.

67. Aurobindo has made, and will continue to make, substantial preparations in the United States to manufacture, use, offer to sell, sell, and/or import Aurobindo's generic bromfenac ophthalmic solution before the expiration of the '131 patent, including Aurobindo's filing of

ANDA No. 212964.

68. Upon information and belief, any commercial manufacture, use, offer for sale, sale, and/or importation of Aurobindo's generic bromfenac ophthalmic solution will directly infringe, contributorily infringe, and/or induce infringement of at least one claim of the '131 patent.

69. Plaintiffs are entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, sale, and/or importation of Aurobindo's generic bromfenac ophthalmic solution will constitute infringement of at least one claim of the '131 patent.

### **COUNT VII AGAINST AUROBINDO**

#### **Infringement of the '813 Patent under § 271(e)(2)**

70. Paragraphs 1-69 are incorporated herein as set forth above.

71. Under 35 U.S.C. § 271(e)(2), Aurobindo has infringed at least one claim of the '813 patent by submitting, or causing to be submitted, to the FDA ANDA No. 212964 seeking approval for the commercial marketing of Aurobindo's generic bromfenac ophthalmic solution before the expiration of the '813 patent.

72. Upon information and belief, Aurobindo's generic bromfenac ophthalmic solution will, if approved and marketed, infringe at least one claim of the '813 patent.

73. Upon information and belief, Aurobindo will, through the manufacture, use, import, offer for sale, and/or sale of Aurobindo's generic bromfenac ophthalmic solution, directly infringe, contributorily infringe, and/or induce infringement of at least one claim of the '813 patent.

74. If Aurobindo's marketing and sale of its generic bromfenac ophthalmic solution prior to the expiration of the '813 patent is not enjoined, Plaintiffs will suffer substantial and irreparable harm for which there is no adequate remedy at law.

### **COUNT VIII AGAINST AUROBINDO**

#### **Declaratory Judgment of Infringement of the '813 Patent**

75. Paragraphs 1-74 are incorporated herein as set forth above.

76. These claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

77. There is an actual case or controversy such that the Court may entertain Plaintiffs' request for declaratory relief consistent with Article III of the United States Constitution, and this actual case or controversy requires a declaration of rights by this Court.

78. Aurobindo has made, and will continue to make, substantial preparations in the United States to manufacture, use, offer to sell, sell, and/or import Aurobindo's generic bromfenac ophthalmic solution before the expiration of the '813 patent, including Aurobindo's filing of ANDA No. 212964.

79. Upon information and belief, any commercial manufacture, use, offer for sale, sale, and/or importation of Aurobindo's generic bromfenac ophthalmic solution will directly infringe, contributorily infringe, and/or induce infringement of at least one claim of the '813 patent.

80. Plaintiffs are entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, sale, and/or importation of Aurobindo's generic bromfenac ophthalmic solution will constitute infringement of at least one claim of the '813 patent.

### **COUNT IX AGAINST AUROBINDO**

#### **Infringement of the '606 Patent under § 271(e)(2)**

81. Paragraphs 1-80 are incorporated herein as set forth above.

82. Under 35 U.S.C. § 271(e)(2), Aurobindo has infringed at least one claim of the '606 patent by submitting, or causing to be submitted, to the FDA ANDA No. 212964 seeking approval

for the commercial marketing of Aurobindo's generic bromfenac ophthalmic solution before the expiration of the '606 patent.

83. Upon information and belief, Aurobindo's generic bromfenac ophthalmic solution will, if approved and marketed, infringe at least one claim of the '606 patent.

84. Upon information and belief, Aurobindo will, through the manufacture, use, import, offer for sale, and/or sale of Aurobindo's generic bromfenac ophthalmic solution, directly infringe, contributorily infringe, and/or induce infringement of at least one claim of the '606 patent.

85. If Aurobindo's marketing and sale of its generic bromfenac ophthalmic solution prior to the expiration of the '606 patent is not enjoined, Plaintiffs will suffer substantial and irreparable harm for which there is no adequate remedy at law.

### **COUNT X AGAINST AUROBINDO**

#### **Declaratory Judgment of Infringement of the '606 Patent**

86. Paragraphs 1-85 are incorporated herein as set forth above.

87. These claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

88. There is an actual case or controversy such that the Court may entertain Plaintiffs' request for declaratory relief consistent with Article III of the United States Constitution, and this actual case or controversy requires a declaration of rights by this Court.

89. Aurobindo has made, and will continue to make, substantial preparations in the United States to manufacture, use, offer to sell, sell, and/or import Aurobindo's generic bromfenac ophthalmic solution before the expiration of the '606 patent, including Aurobindo's filing of ANDA No. 212964.

90. Upon information and belief, any commercial manufacture, use, offer for sale, sale,

and/or importation of Aurobindo's generic bromfenac ophthalmic solution will directly infringe, contributorily infringe, and/or induce infringement of at least one claim of the '606 patent.

91. Plaintiffs are entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, sale, and/or importation of Aurobindo's generic bromfenac ophthalmic solution will constitute infringement of at least one claim of the '606 patent.

### **COUNT XI AGAINST AUROBINDO**

#### **Infringement of the '609 Patent under § 271(e)(2)**

92. Paragraphs 1-91 are incorporated herein as set forth above.

93. Under 35 U.S.C. § 271(e)(2), Aurobindo has infringed at least one claim of the '609 patent by submitting, or causing to be submitted, to the FDA ANDA No. 212964 seeking approval for the commercial marketing of Aurobindo's generic bromfenac ophthalmic solution before the expiration of the '609 patent.

94. Upon information and belief, Aurobindo's generic bromfenac ophthalmic solution will, if approved and marketed, infringe at least one claim of the '609 patent.

95. Upon information and belief, Aurobindo will, through the manufacture, use, import, offer for sale, and/or sale of Aurobindo's generic bromfenac ophthalmic solution, directly infringe, contributorily infringe, and/or induce infringement of at least one claim of the '609 patent.

96. If Aurobindo's marketing and sale of its generic bromfenac ophthalmic solution prior to the expiration of the '609 patent is not enjoined, Plaintiffs will suffer substantial and irreparable harm for which there is no adequate remedy at law.

### **COUNT XII AGAINST AUROBINDO**

#### **Declaratory Judgment of Infringement of the '609 Patent**

97. Paragraphs 1-96 are incorporated herein as set forth above.



98. These claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

99. There is an actual case or controversy such that the Court may entertain Plaintiffs' request for declaratory relief consistent with Article III of the United States Constitution, and this actual case or controversy requires a declaration of rights by this Court.

100. Aurobindo has made, and will continue to make, substantial preparations in the United States to manufacture, use, offer to sell, sell, and/or import Aurobindo's generic bromfenac ophthalmic solution before the expiration of the '609 patent, including Aurobindo's filing of ANDA No. 212964.

101. Upon information and belief, any commercial manufacture, use, offer for sale, sale, and/or importation of Aurobindo's generic bromfenac ophthalmic solution will directly infringe, contributorily infringe, and/or induce infringement of at least one claim of the '609 patent.

102. Plaintiffs are entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, sale, and/or importation of Aurobindo's generic bromfenac ophthalmic solution will constitute infringement of at least one claim of the '609 patent.

### **COUNT XIII AGAINST AUROBINDO**

#### **Infringement of the '220 Patent under § 271(e)(2)**

103. Paragraphs 1-102 are incorporated herein as set forth above.

104. Under 35 U.S.C. § 271(e)(2), Aurobindo has infringed at least one claim of the '220 patent by submitting, or causing to be submitted, to the FDA ANDA No. 212964 seeking approval for the commercial marketing of Aurobindo's generic bromfenac ophthalmic solution before the expiration of the '220 patent.

105. Upon information and belief, Aurobindo's generic bromfenac ophthalmic solution

will, if approved and marketed, infringe at least one claim of the '220 patent.

106. Upon information and belief, Aurobindo will, through the manufacture, use, import, offer for sale, and/or sale of Aurobindo's generic bromfenac ophthalmic solution, directly infringe, contributorily infringe, and/or induce infringement of at least one claim of the '220 patent.

107. If Aurobindo's marketing and sale of its generic bromfenac ophthalmic solution prior to the expiration of the '220 patent is not enjoined, Plaintiffs will suffer substantial and irreparable harm for which there is no adequate remedy at law.

#### **COUNT XIV AGAINST AUROBINDO**

##### **Declaratory Judgment of Infringement of the '220 Patent**

108. Paragraphs 1-107 are incorporated herein as set forth above.

109. These claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

110. There is an actual case or controversy such that the Court may entertain Plaintiffs' request for declaratory relief consistent with Article III of the United States Constitution, and this actual case or controversy requires a declaration of rights by this Court.

111. Aurobindo has made, and will continue to make, substantial preparations in the United States to manufacture, use, offer to sell, sell, and/or import Aurobindo's generic bromfenac ophthalmic solution before the expiration of the '220 patent, including Aurobindo's filing of ANDA No. 212964.

112. Upon information and belief, any commercial manufacture, use, offer for sale, sale, and/or importation of Aurobindo's generic bromfenac ophthalmic solution will directly infringe, contributorily infringe, and/or induce infringement of at least one claim of the '220 patent.

113. Plaintiffs are entitled to a declaratory judgment that future commercial

manufacture, use, offer for sale, sale, and/or importation of Aurobindo's generic bromfenac ophthalmic solution will constitute infringement of at least one claim of the '220 patent.

#### **COUNT XV AGAINST AUROBINDO**

##### **Infringement of the '277 Patent under § 271(e)(2)**

114. Paragraphs 1-113 are incorporated herein as set forth above.

115. Under 35 U.S.C. § 271(e)(2), Aurobindo has infringed at least one claim of the '277 patent by submitting, or causing to be submitted, to the FDA ANDA No. 212964 seeking approval for the commercial marketing of Aurobindo's generic bromfenac ophthalmic solution before the expiration of the '277 patent.

116. Upon information and belief, Aurobindo's generic bromfenac ophthalmic solution will, if approved and marketed, infringe at least one claim of the '277 patent.

117. Upon information and belief, Aurobindo will, through the manufacture, use, import, offer for sale, and/or sale of Aurobindo's generic bromfenac ophthalmic solution, directly infringe, contributorily infringe, and/or induce infringement of at least one claim of the '277 patent.

118. If Aurobindo's marketing and sale of its generic bromfenac ophthalmic solution prior to the expiration of the '277 patent is not enjoined, Plaintiffs will suffer substantial and irreparable harm for which there is no adequate remedy at law.

#### **COUNT XVI AGAINST AUROBINDO**

##### **Declaratory Judgment of Infringement of the '277 Patent**

119. Paragraphs 1-118 are incorporated herein as set forth above.

120. These claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

121. There is an actual case or controversy such that the Court may entertain Plaintiffs'

request for declaratory relief consistent with Article III of the United States Constitution, and this actual case or controversy requires a declaration of rights by this Court.

122. Aurobindo has made, and will continue to make, substantial preparations in the United States to manufacture, use, offer to sell, sell, and/or import Aurobindo's generic bromfenac ophthalmic solution before the expiration of the '277 patent, including Aurobindo's filing of ANDA No. 212964.

123. Upon information and belief, any commercial manufacture, use, offer for sale, sale, and/or importation of Aurobindo's generic bromfenac ophthalmic solution will directly infringe, contributorily infringe, and/or induce infringement of at least one claim of the '277 patent.

124. Plaintiffs are entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, sale, and/or importation of Aurobindo's generic bromfenac ophthalmic solution will constitute infringement of at least one claim of the '277 patent.

### **COUNT XVII AGAINST AUROBINDO**

#### **Infringement of the '958 Patent under § 271(e)(2)**

125. Paragraphs 1-124 are incorporated herein as set forth above.

126. Under 35 U.S.C. § 271(e)(2), Aurobindo has infringed at least one claim of the '958 patent by submitting, or causing to be submitted, to the FDA ANDA No. 212964 seeking approval for the commercial marketing of Aurobindo's generic bromfenac ophthalmic solution before the expiration of the '958 patent.

127. Upon information and belief, Aurobindo's generic bromfenac ophthalmic solution will, if approved and marketed, infringe at least one claim of the '958 patent.

128. Upon information and belief, Aurobindo will, through the manufacture, use, import, offer for sale, and/or sale of Aurobindo's generic bromfenac ophthalmic solution, directly

infringe, contributorily infringe, and/or induce infringement of at least one claim of the '958 patent.

129. If Aurobindo's marketing and sale of its generic bromfenac ophthalmic solution prior to the expiration of the '958 patent is not enjoined, Plaintiffs will suffer substantial and irreparable harm for which there is no adequate remedy at law.

### **COUNT XVIII AGAINST AUROBINDO**

#### **Declaratory Judgment of Infringement of the '958 Patent**

130. Paragraphs 1-129 are incorporated herein as set forth above.

131. These claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

132. There is an actual case or controversy such that the Court may entertain Plaintiffs' request for declaratory relief consistent with Article III of the United States Constitution, and this actual case or controversy requires a declaration of rights by this Court.

133. Aurobindo has made, and will continue to make, substantial preparations in the United States to manufacture, use, offer to sell, sell, and/or import Aurobindo's generic bromfenac ophthalmic solution before the expiration of the '958 patent, including Aurobindo's filing of ANDA No. 212964.

134. Upon information and belief, any commercial manufacture, use, offer for sale, sale, and/or importation of Aurobindo's generic bromfenac ophthalmic solution will directly infringe, contributorily infringe, and/or induce infringement of at least one claim of the '958 patent.

135. Plaintiffs are entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, sale, and/or importation of Aurobindo's generic bromfenac ophthalmic solution will constitute infringement of at least one claim of the '958 patent.

**PRAYER FOR RELIEF**

**WHEREFORE**, Plaintiffs respectfully request that the Court enter judgment in their favor and against Aurobindo on the patent infringement claims set forth above and respectfully request that this Court:

1. enter judgment that, under 25 U.S.C. § 271(e)(2), Aurobindo has infringed at least one claim of the '431 patent by submitting or causing to be submitted ANDA No. 212964 to the FDA to obtain approval for the commercial manufacture, use, import, offer for sale, and/or sale in the United States of Aurobindo's generic bromfenac ophthalmic solution before the expiration of the '431 patent;

2. enter judgment that, under 25 U.S.C. § 271(e)(2), Aurobindo has infringed at least one claim of the '290 patent by submitting or causing to be submitted ANDA No. 212964 to the FDA to obtain approval for the commercial manufacture, use, import, offer for sale, and/or sale in the United States of Aurobindo's generic bromfenac ophthalmic solution before the expiration of the '290 patent;

3. enter judgment that, under 25 U.S.C. § 271(e)(2), Aurobindo has infringed at least one claim of the '131 patent by submitting or causing to be submitted ANDA No. 212964 to the FDA to obtain approval for the commercial manufacture, use, import, offer for sale, and/or sale in the United States of Aurobindo's generic bromfenac ophthalmic solution before the expiration of the '131 patent;

4. enter judgment that, under 25 U.S.C. § 271(e)(2), Aurobindo has infringed at least one claim of the '813 patent by submitting or causing to be submitted ANDA No. 212964 to the FDA to obtain approval for the commercial manufacture, use, import, offer for sale, and/or sale in the United States of Aurobindo's generic bromfenac ophthalmic solution before the expiration of

the '813 patent;

5. enter judgment that, under 25 U.S.C. § 271(e)(2), Aurobindo has infringed at least one claim of the '606 patent by submitting or causing to be submitted ANDA No. 212964 to the FDA to obtain approval for the commercial manufacture, use, import, offer for sale, and/or sale in the United States of Aurobindo's generic bromfenac ophthalmic solution before the expiration of the '606 patent;

6. enter judgment that, under 25 U.S.C. § 271(e)(2), Aurobindo has infringed at least one claim of the '609 patent by submitting or causing to be submitted ANDA No. 212964 to the FDA to obtain approval for the commercial manufacture, use, import, offer for sale, and/or sale in the United States of Aurobindo's generic bromfenac ophthalmic solution before the expiration of the '609 patent;

7. enter judgment that, under 25 U.S.C. § 271(e)(2), Aurobindo has infringed at least one claim of the '220 patent by submitting or causing to be submitted ANDA No. 212964 to the FDA to obtain approval for the commercial manufacture, use, import, offer for sale, and/or sale in the United States of Aurobindo's generic bromfenac ophthalmic solution before the expiration of the '220 patent;

8. enter judgment that, under 25 U.S.C. § 271(e)(2), Aurobindo has infringed at least one claim of the '277 patent by submitting or causing to be submitted ANDA No. 212964 to the FDA to obtain approval for the commercial manufacture, use, import, offer for sale, and/or sale in the United States of Aurobindo's generic bromfenac ophthalmic solution before the expiration of the '277 patent;

9. enter judgment that, under 25 U.S.C. § 271(e)(2), Aurobindo has infringed at least one claim of the '958 patent by submitting or causing to be submitted ANDA No. 212964 to the

FDA to obtain approval for the commercial manufacture, use, import, offer for sale, and/or sale in the United States of Aurobindo's generic bromfenac ophthalmic solution before the expiration of the '958 patent;

10. order that the effective date of any approval by the FDA of Aurobindo's generic bromfenac ophthalmic solution be a date that is not earlier than the expiration of the '431 patent, the '290 patent, the '131 patent, the '813 patent, the '606 patent, the '609 patent, the '220 patent, the '277 patent, and the '958 patent, or such later date as the Court may determine;

11. enjoin Aurobindo from the commercial manufacture, use, import, offer for sale, and/or sale of Aurobindo's generic bromfenac ophthalmic solution until expiration of the '431 patent, the '290 patent, the '131 patent, the '813 patent, the '606 patent, the '609 patent, the '220 patent, the '277 patent, and the '958 patent, or such later date as the Court may determine;

12. enjoin Aurobindo and all persons acting in concert with Aurobindo from seeking, obtaining, or maintaining approval of Aurobindo's ANDA No. 212964 until expiration of the '431 patent, the '290 patent, the '131 patent, the '813 patent, the '606 patent, the '609 patent, the '220 patent, the '277 patent, and the '958 patent;

13. declare this to be an exceptional case under 35 U.S.C. §§ 285 and 271(e)(4) and award Plaintiffs' costs, expenses, and disbursements in this action, including reasonable attorney's fees;

14. award Plaintiffs such further and additional relief as this Court deems just and proper.



Dated: June 3, 2019  
Newark, New Jersey

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**CERTIFICATION OF NON-ARBITRABILITY**  
**PURSUANT TO LOCAL CIVIL RULE 201.1(d)**

Pursuant to Local Civil Rule 201.1(d), the undersigned counsel hereby certifies that this action seeks declaratory and injunctive relief and, therefore, is not subject to mandatory arbitration.

I certify under penalty of perjury that the foregoing is true and correct.

Dated: June 3, 2019  
Newark, New Jersey

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